UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WISCONSIN

SHERRI CUMMISFORD, on behalf of herself and all others similarly situated, Plaintiff, v. SHIRE U.S., INC.; SHIRE, LLC, ACTAVIS ELIZABETH LLC, ACTAVIS INC., and JOHN DOES 1-100; ABC CORPS 1-100, inclusive, Defendants.	Case No.: 16-cv-1570 **Class Action** **Jury Trial Demanded**

CLASS ACTION COMPLAINT

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Plaintiff, Sherri Cummisford, individually and on behalf of all others similarly situated (the "Class"), brings this action against Defendants Shire LLC and Shire U.S., Inc. (collectively, "Shire"), and Actavis Elizabeth LLC and Actavis Inc. (collectively, "Actavis") and allege, based on personal knowledge, investigation of counsel, and information and belief as to all other matters, as follows:

I. NATURE OF ACTION

1. This is a putative class action comprised of consumer indirect purchasers of Intuniv® ("Intuniv"), the popular branded once-daily, extended-release formulation of the prescription medication guanfacine hydrochloride (guanfacine) prescribed for pediatric and adolescent patients to treat attention deficit hyperactivity disorder ("ADHD"). Shire delayed generic entry of Intuniv for approximately two (2) years through sham patent litigation against generic guanfacine manufacturers and by entering into anticompetitive reverse payment settlement agreements with Actavis. As a result, Shire and Actavis, individually and collectively, were able to retain tens of millions of dollars in anticompetitive profits at the expense of consumers.

2. Shire manufactures and sells Intuniv, which is a non-stimulant (thus non-DEA scheduled) branded ADHD medication that was first approved by the Food and Drug Administration ("FDA") on September 2, 2009.

3. The active ingredient of Intuniv – guanfacine hydrochloride – was first introduced to the market in 1986 under the brand name Tenex® ("Tenex") as a new molecular entity ("NME") for the treatment of hypertension. As of Intuniv's approval in 2009 for ADHD, the active ingredient formulation of guanfacine hydrochloride had been off patent and in the public domain for years.

4. Branded pharmaceutical drugs are submitted to the U.S. Food and Drug Administration ("FDA") through a New Drug Application ("NDA") pursuant to 21 U.S.C. § 355, *et seq.* The FDA approves the NDA upon a showing – through several randomized controlled clinical trials – that the drug is safe and effective for the proposed indication.

5. Generic drugs are prescription drugs that contain the same active ingredient as their branded counterparts. In contrast to the extensive clinical trial requirements for branded drugs, generic drug approval is subject to the Hatch-Waxman Act of 1984, 21 U.S.C. § 355(j), *et seq.*, which was enacted by Congress to streamline generic drug approval and encourage generic drug competition.

6. Generic drug applications are referred to as Abbreviated New Drug Applications ("ANDAs"), and are approved by the FDA upon a showing that the ANDA product is bioequivalent (i.e., no substantial differences) and bioequivalent to the FDA-approved reference listed drug ("RLD"), which usually refers to an NDA drug. Upon granting final approval for a generic drug, the FDA will typically state the generic drug is "therapeutically equivalent" to the branded drug. The FDA codes generic drugs as "A/B rated" to the RLD branded drug.

7. Patients and their prescribing physicians can thus expect to substitute "A/B rated" generic drugs with the full expectation that the generic drug will carry the same safety and efficacy profile as the branded RLD. Generic drug approval is streamlined because generic drugs are typically sold at much lower prices than their branded equivalents.

8. The branded pharmaceutical company may also elect to license what is commonly referred to as an "Authorized Generic" version of its branded drug. "Authorized Generic" drugs are launched by brand manufacturers as a means to retain revenue upon generic entry, and typically involve the brand manufacturer licensing its NDA formulation (as well as any

intellectual property) to an authorized generic partner. The licensee partner then sells the authorized generic as a generic version of the brand drug (including during any generic exclusivity period, *infra*), and remits a royalty to the brand manufacturer. For major drugs, the licensing of an authorized generic has become commonplace.

9. Upon the market entry of a generic drug, substitution of the brand drug for the generic ("generic substitution" or "generic erosion") occurs very swiftly. Typically, the brand drug (which holds 100% market share as of generic entry) will lose as much as 70% within weeks of generic entry. By one year, the process of generic erosion usually results in the brand drug holding 10% or less market share, with generic equivalents capturing the remaining 90% or greater.

10. Generic erosion occurred even more swiftly in the case of Intuniv, as reported by Shire. In its July 2015 Securities and Exchange Commission ("SEC") Second Quarter 10-Q filing, Shire reported that branded Intuniv market share was a mere 9% within six (6) months of generic entry, with generics capturing 91% of the market.

11. Price erosion occurs swiftly as well. As more generics enter the market, a price collapse occurs, with generic price erosion reaching approximately 90%. With multiple generics on the market, generic drugs prices may fall to as low as 10% of pre-generic entry brand price.

12. There are several forces that drive generic substitution. First, most states have generic substitution laws that mandate and require pharmacies to substitute therapeutically equivalent generics absent exceptional circumstances. These statutes are enacted as consumer protection laws, and are designed to ensure that consumers benefit from the availability of less costly medications.

13. Second, managed care organizations ("MCOs") including health insurance companies and pharmacy benefits managers ("PBMs") – as entities that reimburse a large portion of prescription drug costs – encourage such substitution by their insured patients and physicians through the use of prescription drug formularies. Prescription drug formularies have been implemented by MCOs as a cost-sharing mechanism to control ever-increasing prescription drug costs and to encourage insured patients to utilize cheaper drugs. As co-payors for prescription drugs, it is in both the insurer's and the insured's interest that less expensive generic equivalents be utilized when available. MCOs routinely place generic drugs on the lowest co-payment tier of the formulary, while branded medications are found on higher co-payment tiers.

14. Shire's patent protection on Intuniv ended on September 2, 2013. Shire extended its original patent protection by asserting patents of dubious validity and by prosecuting weak patent litigation against its generic rivals. Thereafter, Shire entered into reverse payment settlement agreements, with the active aid, consent and assistance of Actavis and successfully delayed the entry of generic competition for Intuniv for approximately two (2) years, extending the brand medication pricing and thus costing consumers hundreds of millions of dollars.

15. Defendants' conduct constitutes an illegal restraint of trade, illegal monopoly, unlawful attempted monopolization, and/or an unlawful combination or conspiracy to monopolize in violation of both federal and state antitrust statutes, as well as state consumer protection acts, which harmed consumers by delaying generic entry.

16. Plaintiff therefore brings this action on behalf of herself and similarly situated indirect purchasers of Intuniv and generic Intuniv, asserting that Defendants' anticompetitive, unfair, fraudulent, and/or deceptive behavior violates Wisconsin state law.

II. PARTIES

17. Plaintiff Sherri Cummisford is a citizen and resident of Milwaukee County, Wisconsin. During the Class Period, Mrs. Cummisford's minor child was prescribed Intuniv in Milwaukee County for purposes other than resale.

18. Defendant Shire U.S., Inc. is a New Jersey corporation with a registered agent located in West Trenton, New Jersey 08628 and its principal place of business and headquarters at 300 Shire Way, Lexington, Massachusetts 02421. Throughout the Class Period, Shire U.S., Inc. marketed and sold Intuniv in Wisconsin and elsewhere. Upon information and belief, Shire U.S., Inc. is the manufacturer and distributor of Intuniv.

19. Defendant Shire LLC is a Kentucky limited liability company with its principal place of business at 9200 Brookfield Court, Florence, Kentucky 41042. Shire LLC is a successor entity to Shire Laboratories, Inc., a party to the anticompetitive reverse payment agreements at issue herein. Shire LLC develops, manufactures, and sells brand and generic pharmaceutical products in the United States, including Intuniv. Throughout the Class Period, Shire LLC marketed and sold Intuniv in Wisconsin and elsewhere.

20. Defendant Actavis Elizabeth LLC is a Delaware corporation with its principal place of business in New Jersey. Upon information and belief, Actavis Elizabeth LLC is a party to one of the anticompetitive reverse payment agreements at issue herein. Actavis Elizabeth LLC develops, manufactures, markets, and sells generic pharmaceutical products in the United States. Through the Class Period, Actavis Elizabeth conducted business in Wisconsin and elsewhere.

21. Defendant Actavis Inc. is a Delaware corporation with its principal place of business in New Jersey. Upon information and belief, Actavis Inc. controls and/or dominates Actavis Elizabeth LLC. Actavis Inc. develops, manufactures, markets, and sells generic

pharmaceutical products in the United States. Through the Class Period, Actavis Inc. conducted business in Wisconsin and elsewhere.

22. The true names and capacities, whether individual, corporate, associated or otherwise of certain manufacturers, distributors, or their alter egos that are sued herein as JOHN DOES 1-100 inclusive are presently unknown to Plaintiff, who therefore sues these Defendants by fictitious names. Plaintiff will seek leave of this Court to amend the Complaint to show their true names and capacities when the same have been established. Plaintiff is informed and believes and based thereon alleges that JOHN DOES 1-100 were authorized to do and did business in Wisconsin and elsewhere in the United States. Plaintiff is further informed and believes and based thereon alleges that JOHN DOES 1-100 were or are, in some manner or way, responsible for and liable to Plaintiff for the events, happenings, and damages hereinafter set forth below.

23. Plaintiff is informed and believes and based thereon alleges that at all times relevant herein each of the Defendants was the agent, servant, employee, subsidiary, affiliate, partner, assignee, successor-in-interest, alter ego, or other representative of each of the remaining Defendants and was acting in such capacity in doing some or all of the things herein complained of and alleged.

III. JURISDICTION

24. This Complaint is brought pursuant to, among other things, the Wisconsin Antitrust Act, Wis. Stat. § 133.03, *et seq.*, to seek redress for Defendants' unfair methods of competition, unconscionable acts or practices, and unfair or deceptive conduct in violation of state law.

25. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(d) because the matter in controversy exceeds the sum of $5,000,000, exclusive of interest and costs, and is a class action in which at least one member of the Class is a citizen of a different state than Defendants.

26. Defendants have sufficient minimum contacts with this District or otherwise have intentionally availed themselves of the consumer markets within this District through the promotion, sale, marketing, and/or distribution of its products in this District and/or to this District's residents to render the exercise of jurisdiction by this District's courts permissible under traditional notions of fair play and substantial justice.

27. Defendants transact business within this District, and the interstate trade and commerce described herein is carried out, in substantial part, in this District. Shire is headquartered in this District, and caused the harm alleged herein to emanate, in at least substantial part, from and/or within this District to Class Members within as well as outside this District. Shire and Actavis receive substantial compensation and profits from sales of Intuniv Product in this District. Thus, their liability arose in part in this District. Venue is therefore appropriate under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c).

IV. FACTUAL ALLEGATIONS

A. Intuniv Was a Significant Source of Shire Revenue

28. Intuniv is a non-stimulant central alpha$_{2A}$-adrenergic receptor agonist indicated for the treatment of ADHD as monotherapy and adjunctive therapy to stimulant medications.

29. The active ingredient of Intuniv is guanfacine hydrochloride. Guanfacine hydrochloride was first introduced to the market in 1986 as Tenex. Active ingredient patents for guanfacine hydrochloride have long expired.

30. Shire developed Intuniv as an extended release version of guanfacine hydrochloride, and the FDA approved its NDA on September 2, 2009.

31. Shire – which offers a variety of branded ADHD medicines – sought to market Intuniv as an alternative to stimulant-based ADHD therapies, such as amphetamine-based products (e.g., Adderall) and methylphenidate (e.g., Ritalin). Intuniv enjoyed a successful launch, gaining more than 2% of the ADHD market within six (6) months. Intuniv peaked at approximately 5% of the ADHD market, and in 2013 – Shire's last full year of exclusivity – net sales for Intuniv were $334 million.

B. Hatch-Waxman Background

32. The Drug Price Competition and Patent Term Restoration Act of 1984 – more commonly referred to as the Hatch-Waxman Act – is codified at 21 U.S.C. § 355(j).

33. The stated purpose of Hatch-Waxman is to strike a balance between rewarding genuine innovation and drug discovery by affording longer periods of brand drug marketing exclusivity while at the same time encouraging generic patent challenge and streamlining generic drug competition so that consumers gain the benefit of generic drugs at lower prices as quickly as possible.

34. Brand drug companies submitting a New Drug Application ("NDA") are required to demonstrate clinical safety and efficacy through well-designed clinical trials. 21 U.S.C. § 355 *et seq.*

35. By contrast, generic drug companies submit an Abbreviated New Drug Application ("ANDA"). Instead of demonstrating clinical safety and efficacy, generic drug companies need only demonstrate bioequivalence to the brand or reference listed drug ("RLD"). Bioequivalence is the "absence of significant difference" in the pharmacokinetic profiles of two pharmaceutical products. 21 C.F.R. § 320.1(e).

36. The bioequivalence basis for ANDA approval is premised on the generally accepted proposition that equivalence of pharmacokinetic profiles of two drug products is

accepted as evidence of therapeutic equivalence. In other words, if (1) the RLD is proven to be safe and effective for the approved indication through well-designed clinical studies accepted by the FDA, and (2) the generic company has shown that its ANDA product is bioequivalent to the RLD, then (3) the generic ANDA product must be safe and effective for the same approved indication as the RLD.

37. To encourage generic companies to challenge weak or improperly listed patents, the Hatch-Waxman Act sets up an artificial act of infringement to allow patent litigation to commence as soon as possible. When a generic company files an ANDA, it is required to submit to the FDA a certification regarding the patent status of the RLD. 21 U.S.C. § 355(j)(2)(A)(vii). If the ANDA applicant seeks to market its drug prior to expiration of a listed patent, it must submit a certification asserting that "such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." § 355(j)(2)(A)(vii)(IV). This is commonly referred to as a "Paragraph IV certification."

38. A generic company must then serve upon the patent owner and NDA holder a notice letter regarding its Paragraph IV certification. The Hatch-Waxman Act then provides the patent/NDA holder forty-five (45) days in which to file a patent infringement suit. If such a suit is filed within this timeframe, Hatch-Waxman provides for a thirty (30) month stay on FDA approval of the ANDA. 21 U.S.C. § 355(j)(5)(B)(iii).

39. After expiration of the 30 month stay (unless a court has prior to this entered judgment that the patent is invalid, unenforceable, or not infringed), FDA may approve the ANDA, at which point the generic company may commercially market its ANDA product either "at risk" (if there has not been a final resolution of the patent litigation) or without risk (by waiting until conclusion of the patent litigation). 21 U.S.C. § 355(j)(5)(B)(iii).

40. As an inducement to challenge weak or improperly listed patents, Hatch-Waxman rewards the first generic company to file a substantially complete ANDA containing a Paragraph IV certification with a 180-day period of marketing exclusivity. 21 U.S.C. § 355(j)(5)(B)(iv). The 180-day exclusivity period is triggered upon either a first commercial marketing of the drug (including of the RLD) by the 180-day exclusivity holder or the date on which a court has entered a judgment finding that the patent subject to the Paragraph IV certification is invalid, unenforceable, or not infringed.

C. Intuniv's Hatch-Waxman Exclusivity and Patent Portfolio

41. Upon approval of Intuniv on September 2, 2009, Shire received a Hatch-Waxman regulatory exclusivity period that lasted until September 2, 2012. However, seeking to extend its Intuniv monopoly beyond September 2012, Shire asserted patents of dubious validity concerning the method of use and the extended release formulation for Intuniv tablets.

42. Shire's Intuniv patent portfolio consists of U.S. Patent Nos. 5,854,290 ('290 Patent), which is a now-invalidated (discussed *infra*) method-of-use patent, and U.S. Patent Nos. 6,287,599 ('599 Patent) and 6,811,794 ('794 Patent), which cover the sustained release coating allowing for the extended release of the active ingredients.

43. Patents are intended to encourage innovation by offering a monopoly period for inventions that are novel, useful, and non-obvious. However, the reality is that a large number of issued patents should have been rejected. A 2003 report by the Federal Trade Commission ("FTC") found that the average patent application gets approximately 15-20 hours of review time by the U.S. Patent and Trademark Office's ("PTO") assigned examiner. Despite the PTO receiving hundreds of thousands of patent applications each year, approximately eighty-five percent (85%) of patent applications ultimately result in an issued patent.

44. Brand pharmaceutical companies seeking to take advantage of the PTO's limited resources have increasingly applied a patent procurement strategy known as "evergreening." "Evergreened" patents are patents not on the active pharmaceutical ingredient ("API"), but instead are non-API patents on some ancillary aspect of the drug, such as its delivery method or release mechanism. These "evergreened" patents – if litigated to judgment – have a high rate of being found invalid or not infringed.

45. Shire is no stranger to the strategy of evergreening, and its use of evergreened patents to engineer generic delay through anticompetitive reverse payment settlements is a pattern and practice of Shire and part of Shire's business model as a specialty pharmaceutical company. As stated by one analyst:

> Shire's historical strategy of marketing new reformulations of off-patent active ingredients has minimized the costs of drug development, [but] it has also made Shire's patent portfolio weak. Shire has been relying principally on method of use and composition patents for its products, as well as short-term Hatch-Waxman exclusivity and orphan drug exclusivity, rather than on composition of matter patents, which have a generally stronger legal standing.

46. In fact, the pharmaceutical product that made Shire into an industry giant was Adderall®, a mixture of amphetamines that had been off-patent since the 1950's. As with Intuniv, Shire introduced Adderall for the treatment of ADHD, and subsequently acquired patents on a line extension called Adderall XR® based upon an extended release formulation of Adderall. Shire subsequently settled the Adderall XR patent litigation after paying hundreds of millions of dollars in reverse payments to generic challengers.

47. Shire's Intuniv Patent Portfolio consisted of three (3) evergreened patents, one now-invalidated method-of-use patent ('290 Patent) of guanfacine hydrochloride and two extended release formulation patents ('599 and '794 Patents).

48. Numerous Wall Street analysts, generic pharmaceutical companies, and even Shire understood Shire's Intuniv patent protection to be weak. For example, one analyst wrote in late 2011 that "the Intuniv patent estate is formed through what are commonly viewed as weaker formulation and methods-of-use patents covering extended-release guanfacine in the treatment of ADHD."

D. Generic Challenge to Intuniv

49. Intuniv's NDA was approved on September 2, 2009. The pharmacokinetic profile of Intuniv was so easy to copy that – within weeks – multiple generic companies had filed ANDAs related to Intuniv.

50. On or about December 29, 2009, Actavis filed a substantially complete ANDA with the U.S. Food and Drug Administration ("FDA") to manufacture and sell a generic formulation of Intuniv it had developed. Actavis's ANDA included a "Paragraph IV certification" as to all three (3) patents, which as described *supra* is a declaration by the ANDA filer that it believes the patents covering the registered listed drug are either invalid or not infringed by the ANDA product. Upon service of the Paragraph IV certification, the brand company may elect to initiate Hatch-Waxman patent litigation by filing a patent infringement lawsuit within forty-five (45) days. Such an action triggers a stay preventing the FDA from approving the ANDA until the earlier of thirty (30) months has elapsed or the issuance of a "court decision" finding the patents at issue invalid or not infringed by the ANDA drug ("the 30 month stay").

51. Actavis's ANDA, as the first-filed ANDA, entitled Actavis to a lucrative 180-day exclusivity period ("180-day exclusivity"). The 180-day exclusivity is a statutory incentive set forth in the Hatch-Waxman generic drug approval provisions, 21 U.S.C. § 355(j), for generic pharmaceutical companies to challenge brand manufacturers' patents. The first filer's ANDA –

once approved and if containing a Paragraph IV certification – entitles the first filer to 180 days of generic marketing exclusivity during which the FDA cannot approve other generic companies' later-filed ANDAs. The generic pharmaceutical industry trade group, the Generic Pharmaceutical Association ("GPhA") has asserted that the "vast majority" of generic drug profits occur during the 180-day exclusivity period.

52. As set forth in the Hatch-Waxman Act, the 180-day exclusivity commences upon a "first commercial marketing" by the 180-day exclusivity holder (which applies to both ANDA and authorized generic launches) or upon a "court decision" finding the patents invalid, unenforceable, or not infringed.

53. Soon after Actavis filed its ANDA, TWi Pharmaceuticals, Inc. ("TWi") and Anchen Pharmaceuticals, Inc. ("Anchen") filed substantially complete ANDAs on January 25, 2010 and January 28, 2010, respectively. Upon information and belief, TWi had agreed that Anchen would distribute any generic Intuniv in the United States in collaboration with TWi. Hereinafter, TWi and Anchen are referred to as "TWi/Anchen."

54. Actavis and TWi/Anchen each served Paragraph IV notice letters on Shire on or about April 2, 2010 (Actavis) and April 23, 2010 (TWi/Anchen). Other generic manufacturers also served Shire with Paragraph IV notice letters after first-filer Actavis did so, including Teva Pharmaceuticals, Inc. ("Teva").

55. Having been served Paragraph IV letters by Actavis and TWi/Anchen, as well as others, Shire initiated lawsuits in the United States District Court for the District of Delaware. A number of Shire's Hatch-Waxman lawsuits were consolidated into *Shire LLC et al. v. Teva Pharmaceuticals USA Inc., et al.* No. 10cv329 (D. Del.) by order dated August 2, 2010 (the "10cv329 litigation"). The other related cases included: *Shire LLC et al. v. Actavis Elizabeth*

LLC et al., No. 10cv397 (D. Del.) and *Shire LLC et al. v. Anchen Pharmaceuticals Inc. et al.*, No. 10cv484 (D. Del.). The Hatch-Waxman lawsuits filed by Shire (and consolidated into the 10cv329 litigation) triggered 30-month stays, preventing the FDA from approving Actavis' ANDA until October 2012. The FDA was further prevented from approving any other ANDA until 180 days after the triggering of Actavis's 180-day exclusivity period.

56. Other generic entities filed ANDAs thereafter. Watson Pharmaceuticals ("Watson") (a predecessor entity of Actavis), Impax Laboratories, Inc. ("Impax"), Mylan Pharmaceuticals ("Mylan"), and Sandoz Inc. ("Sandoz") all filed ANDAs in 2010, and served Shire with Paragraph IV notice letters in October 2010 (Watson), November 2010 (Impax), March 2011 (Sandoz) and February 2011 (Mylan). Anchen also filed its own ANDA in 2010 (apart from that filed earlier in collaboration with TWi), and served a Paragraph IV letter in October 2010. Shire filed Hatch-Waxman lawsuits against all of these companies (and others which subsequently filed ANDAs of their own, and then served Paragraph IV notice letters on Shire), triggering 30-month stays on generic approvals for the generic companies' products.

E. Shire's Objectively Baseless Assertion of the '290 Method-of-Use Patent

57. Shire asserted all three (3) patents, including the '290 Patent, against Actavis and other generic ANDA filers.

58. The '290 Patent is a so-called "method-of-use" patent claiming a method of treating ADHD using guanfacine. Such method-of-use patents are inherently weak, because it is not the invention itself that is claimed as novel (i.e., the active ingredient), but rather its use to treat a new disease state. Two prominent scholars who have published extensively regarding pharmaceutical patent litigation have described method-of-use patents as "open to challenge" and that such challenges are "often [met] with success." C. Scott Hemphill and Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8(4) J. Emp. Legal Studies 613, 621

(2011); *see also* Jason Brewer, *Updating the Patent System's Novelty Requirement to Promote Small-Molecule Medicinal Progress*, 45 J. Marshall L. Rev. 1151, 1164 (2012) ("Weakness in [pharmaceutical] method of use patents stems from case law and policy, enforcement problems, and easy work-arounds for would-be infringers.").

59. Shire understood that the '290 Patent was exceedingly weak, but nevertheless litigated the patent for as long as possible to prolong its exclusivity. However, on March 22, 2012, Shire dedicated the '290 patent to the public. This occurred just days before Shire would have been required to tender expert reports regarding the '290 Patent in the 10cv329 litigation. As stated by TWi/Anchen, "[Shire] sued Anchen on the '290 patent, proceeded through complete fact discovery, and then, just days before the first expert disclosure date, announced that they were disclaiming the patent." Indeed, Shire's dedication occurred the very same day that the district court issued its claim construction opinion in the consolidated 10cv329 litigation. Shire eventually sought reconsideration of that opinion, which was denied.

60. Nevertheless, the '290 Patent dedication was nothing more than an attempt by Shire and Actavis (the first filer) to game the Hatch-Waxman system and prevent later filers from entering the market.

61. After dedicating the '290 Patent, Shire then sought dismissal of its '290 Patent claims without a judgment against the patent, a move supported by Actavis but vigorously opposed by TWi/Anchen (the second filer). Without a judgment against the '290 Patent, Actavis's exclusivity as to the '290 Patent would be preserved until it launched its generic Intuniv. Thus, even if TWi/Anchen achieved victory against Shire's '599 and '794 Patents (triggering Actavis's exclusivity as to those patents), it still could not have launched a generic Intuniv until 180 days after Actavis's launch because the '290 Patent's exclusivity would have

still been in effect. Such a move would have provided Actavis a guaranteed 180-day exclusivity period without ANDA Intuniv competition. As discussed in further detail below, a guaranteed 180-day exclusivity period for Actavis would have made Shire's agreement not to launch an AG during that period even more valuable to Actavis.

62. TWi/Anchen's counsel noted the collusion between Shire and Actavis in open court: "Think about it, how unusual is it that the first filer and the plaintiff are on the same side of the fence on a legal issue involving the validity of a patent? Why would that be?"

63. Shire's likely calculation was odds-based, anticompetitively motivated, and speaks to the inherent weakness of the '290 Patent as well as Shire's willingness to settle with Actavis on an anticompetitive basis. In other words, Shire thought it more likely that a court would dismiss without judgment the '290 Patent upon Shire's request than affirm the '290 Patent's validity in a merits judgment. However, just getting the '290 Patent dismissed faced long odds, and despite Shire's request, the district court entered judgment against the '290 patent finding it invalid by order entered July 23, 2012.

64. Shire's assertion of the '290 Patent was objectively baseless as Shire did not even present expert witnesses tendering an opinion that the '290 Patent was valid and/or infringed. Further, Shire's attempt (supported by Actavis) to gain a dismissal of the '290 Patent was the first step in an anticompetitive arrangement between the two companies to delay generic Intuniv market entry.

F. Shire's Weak Litigation Position Regarding the '599 and '794 Extended Release Formulation Patents

65. The various litigations regarding the '599 and '794 Patents were not progressing well for Shire either. The '599 and '794 Patents are so-called "formulation" patents covering Intuniv's extended release formulation. As with method-of-use patents, formulation patents are

so-called "secondary" or "evergreened" patents. Such patents are highly susceptible to invalidation by courts or non-infringing work-arounds by competitors.

66. On March 22, 2012, the district court in the 10cv329 litigation entered a claim construction (a/k/a *Markman*) order construing the claim terms of the '599 and '794 Patents. The Court construed claim terms of the '599 and '794 Patents unfavorably to Shire. Other district courts followed suit. *See Shire LLC et al. v. Impax Labs., Inc., et al.*, No. 3:10cv5467, Dkt. No. 180, at 9 (N.D. Cal. June 1, 2012) ("Accordingly, consistent with the Delaware district court's determination of this issue, defendants' urged limitation will be adopted."). Recognizing that it had lost key battles, Shire moved for reconsideration of these claim construction orders. Shire's motions were summarily denied by orders dated June 20, 2012 (10cv329) and October 9, 2012 (10cv5467).

67. TWi/Anchen understood that it had scored a key victory in the 10cv329 case and it moved for summary judgment the day the district court denied Shire's motion for reconsideration of the *Markman* order. As stated in TWi/Anchen's summary judgment, "the Court's claim construction order legally precludes [Shire's] primary argument against Anchen …." TWi/Anchen was equally strong in its reply: "Because [Shire] do[es] not like the actual record, [Shire] ha[s] attempted to create a new one notwithstanding that expert discovery closed …."

68. More generally, the 10cv329 case is replete with – in TWi/Anchen's words – "untimely effort[s] by [Shire] to prevent the Court from entering judgment in this matter …." In other words, not only was Shire losing the Intuniv patent litigation, but it was attempting to delay the inevitable through untimely expert disclosures, motions for discovery, and other litigation tactics. The longer the court case dragged out, the longer Shire could maintain its monopoly

position with respect to Intuniv. Shire's conduct underscores the baselessness of its patent litigation, which was designed to delay generic entry rather than to vindicate valid patent rights.

G. Shire Makes Anchen Shire's Authorized Generic at an Unreasonably Low Non-Arm's Length Royalty

69. Not long after TWi/Anchen's summary judgment went under submission, and upon information and belief, the very day that the district court held the pretrial conference, Shire and TWi/Anchen settled the Intuniv patent litigation on or about September 4, 2012. The timing of the TWi/Anchen settlement reflected Shire's doubts about the merits of its patent case. With TWi/Anchen's summary judgment motion under submission, the district court could have entered judgment against Shire at any moment.

70. Furthermore, with trial just weeks away, Shire would have appropriately viewed a negative verdict as imminent.

71. The district court entered the proposed consent judgment on September 12, 2012, just five (5) days prior to trial. The proposed consent judgment misleadingly sought to create the impression to the district court (and subsequent courts) that Shire's Intuniv patents were genuinely valid, enforceable, and infringed by Anchen's generic Intuniv products.

72. With fact and expert discovery complete and with trial just days away, Shire's anticipated future litigation costs would have been minimal.

73. TWi/Anchen's challenges to Shire's patents were likely to succeed.

74. On September 6, 2012, Shire issued a press release concerning the Anchen settlement and license. According to the press release, Anchen would be able to launch its generic Intuniv product on July 1, 2016, "or earlier in certain limited circumstances." Further, Shire's press release states that "under certain circumstances, Shire may authorize Anchen to sell authorized generic versions of INTUNIV supplied by Shire, on which Shire will receive a

significant royalty." Shire never disclosed that it retained complete discretion on whether any AG could be launched by TWi/Anchen.

75. Upon information and belief, Shire's settlement with TWi/Anchen made Anchen Shire's authorized generic ("AG") licensee/distributor, and in the event of an unlicensed Actavis launch (i.e., if Actavis did not later settle with Shire), Anchen could enter the market as Shire's AG to compete with Actavis during Actavis's 180-day generic exclusivity period.

76. The combination of a late date certain by which TWi/Anchen could enter the market with their own generic (i.e., July 1, 2016), plus the ability to sell Shire's AG product, was instrumental in Shire's overarching anticompetitive scheme. By settling with TWi/Anchen first, Shire created anticompetitive leverage over Actavis – the first filer – to settle at non-competitive terms. That is, even if Actavis prevailed at trial in the 10cv329 litigation and began to sell its generic Intuniv product as soon as possible, Shire could undercut Actavis's exclusive, first-filer profits by authorizing TWi/Anchen to start selling a Shire AG product. This would cut into Actavis' anticipated profits in the first 180 days Actavis enjoyed as the first ANDA filer. But, if Actavis settled with Shire, and Shire did not launch an AG product through TWi/Anchen, then Actavis' lucrative 180-day exclusivity would be retained.

77. This is exactly what happened. Shire's settlement with TWi/Anchen transferred significant value to the latter – the right to sell Shire's AG product (with royalties flowing back to Shire) – if Shire chose to launch an AG product. This transfer made little sense given that TWi/Anchen had already litigated the patent litigation to the threshold of trial, and before a ruling on its summary judgment motion, either of which could have extinguished Shire's patent protection and allowed TWi/Anchen to launch its generic product after the expiration of

Actavis's 180-day exclusivity, which certainly would have been sooner than the July 1, 2016 launch date that TWi/Anchen agreed to in its settlements with Shire.

78. This sort of anticompetitive scheming is not novel. Industry and regulatory experts recognize the potential for anticompetitive settlements between pioneer manufacturers (such as Shire) and subsequent ANDA filers (such as TWi/Anchen). Later ANDA filers typically stand to gain little from launching their generic into a previously genericized market. As described *supra*, GPhA has stated that "[t]he vast majority of potential profits for a generic drug manufacturer materialize during the 180-day exclusivity period." Public Comment from GPhA to Federal Trade Comm'n ("FTC") re: Authorized Generic Drug Study, dated June 27, 2006.

79. By contrast, a later ANDA filer can potentially see a revenue windfall by settling its patent litigation with the brand company and becoming the brand's AG to compete with the first filer. The FTC has taken note of such arrangements: "For the litigated product, the brand appoints a subsequent-filer as an AG marketer in competition with the first-filer." And in the event that the first filer settles, the later filer can then launch 180 days after as likely would have happened without a settlement. Thus, such settlements for later filers represent a "win-win" scenario as they either realize additional revenue as the brand's AG or launch in the same position they would have anyway without any legal risk.

80. The FTC holds the position that such settlements with subsequent filers, such as Anchen, may serve to delay generic entry in both a litigation and settlement context. The FTC noted with concern that "[o]ne way that an agreement with a subsequent filer could affect the timing of generic entry is by eliminating a patent challenge that could have precipitated generic competition. By continuing to litigate, a subsequent filer might obtain a court decision … that would trigger the first-filer's exclusivity period or its forfeiture." In the settlement context, the

brand may use the subsequent filer as a means to place additional pressure upon the first filer. Upon information and belief, this is precisely what occurred in the Shire-TWi/Anchen settlement.

81. However, upon information and belief, Shire offered TWi/Anchen an additional inducement to settle aside from the simple "win-win" described above. Such AG licenses made pursuant to a reasonable arm's length transaction routinely yield extremely high royalties, owing to the fact that the AG licensee would not otherwise be able to compete during the hyper-important 180-day exclusivity. Thus, arm's length AG royalties payable to the brand in such situations are typically approximately 90% of net profits. Such royalties may decrease outside the 180-day period, but still remain at a very high percentage of net profits.

82. Upon information and belief, the authorized generic license to TWi/Anchen was negotiated at a commercially unreasonably low royalty rate given the circumstances. In essence, Shire traded a significant number of royalty percentage points to TWi/Anchen in exchange for TWi/Anchen settling its strong patent challenge, with such transfer of value constituting a disguised reverse payment in exchange for settlement and generic delay. Further, on information and belief, Shire retained sole discretion to decide whether TWi/Anchen could sell an AG product.

83. Shire actively and willfully concealed this payment in exchange for settlement. As stated above, Shire's September 6, 2012 press release stated that Shire would receive a "significant royalty." Shire at no point disclosed that it had in fact lowered the royalty with TWi/Anchen in exchange for settlement. In fact, the actual royalty percentage has not been publicly disclosed at all and could not be discovered in the exercise of reasonable diligence.

84. Thus, TWi/Anchen essentially switched from aggressive challenger of Shire's patents to Shire's bedfellow through a secret, sweetheart arrangement that left intact Shire's patents which, to that point, TWi/Anchen had vigorously challenged. As a result of this outcome, Shire put itself in position to negotiate an anticompetitive agreement with Actavis, the first filer.

H. Shire and Actavis Enter an Anticompetitive Settlement, Which Delayed Generic Intuniv By Nearly Two Years

85. Notwithstanding the Shire-TWi/Anchen settlement, the district court held a four (4) day bench trial on the '599 and '794 Patents from September 17-20, 2012, in order to resolve Shire's still-pending claims against Actavis and Teva.

86. Wall Street analysts held dim prospects for Shire at trial. Most analysts concurred that generic Intuniv would be on the market by mid-2013. For example, just days after the Delaware district court summarily denied Shire's reconsideration of the *Markman* order in June 2012, BNP Paribas wrote, "We now adopt a bear scenario with Shire losing the litigation vs generic makers (17 Sept 2012) on the two remaining formulation patents (599'/794') and the entry of generics in mid-2013 after a 6-9 month trial." This sentiment was echoed by other analysts in non-public reports.

87. Upon information and belief, Shire also viewed its prospects of winning the Intuniv litigation as a long shot. Shire also attempted to delay the court's trial opinion through frivolous and non-substantive post-trial motions practice.

88. Meanwhile, the thirty (30) month stay against FDA approval of Actavis's Intuniv ANDA expired in early October 2012, which prompted the FDA to issue final approval to Actavis by letter dated October 5, 2012. The FDA's approval letter further granted Actavis 180 days of marketing exclusivity.

89. Contemporaneous third-party reports suggested Actavis would succeed in its litigation with Shire.

90. In early 2013, Actavis CEO Paul Bisaro echoed the company's belief that time was "of the essence" for any settlement with Shire, because the court's written decision on the bench trial would be "relatively soon."

91. Yet, despite Actavis's belief in an imminent ruling which would pave the way for Actavis's launch of generic Intuniv in short order, on or about April 25, 2013, Shire and Actavis settled the Intuniv patent litigation post-trial but before the Delaware district court issued an opinion. Accordingly, Shire's and Actavis's anticipated future litigation costs at the time of the settlement were negligible.

92. As noted above, settling with TWi/Anchen first let Shire orchestrate an anticompetitive outcome in which (i) Actavis would not launch its generic product until December 1, 2014 (more than two years after Actavis had received FDA approval), (ii) Shire would forego launching its own AG product (thereby avoiding competing with its own branded product), (iii) Actavis would not face competition from a Shire AG product during Actavis's 180-day exclusivity, and (iv) no other generic companies would be able to launch generic products until 180 days after Actavis did so.

93. According to Shire's and Actavis's press releases dated April 25, 2013, Actavis would be able to launch its generic Intuniv on December 1, 2014, and would pay Shire 25% royalties on gross profits. Actavis's press release further stated that "[o]ther details of the settlement were not disclosed." On information and belief, the 25% royalty rate was an unreasonable, commercially low rate, alone or in conjunction with other terms of the settlement, that represents a disguised, large transfer of value from Shire to Actavis.

94. Despite providing for a delayed generic entry date a full year and a half later than expectations, Actavis's CEO Paul Bisaro falsely asserted that "consumers will benefit from an earlier launch of a guanfacine hydrochloride product," concealing the true nature of the settlement and its terms.

95. In exchange for such a substantial generic delay, upon information and belief, Shire agreed, among other things, not to launch an AG to compete with Actavis during its highly valuable 180-day exclusivity period. Upon information and belief, Shire's earlier settlement with Anchen provided Shire the ability to enter into a settlement with Actavis that included a so-called "No AG" agreement. This represents a large, and unjustified, transfer of value from Shire to Actavis, insofar as Shire gave up potentially millions of dollars that it could have earned had it launched an AG product during Actavis's 180-day exclusivity.

96. Indeed, it has become commonplace for brand companies to launch AGs to compete for market share with the first-filer during the 180-day exclusivity period. For example, during the period 2003-2008, the FTC found that 19 of 24 of the largest selling drugs with an exclusivity period saw an authorized generic. Notably, this figure would have been higher but for some of the settlements containing a non-compete/no-AG clause. As discussed *supra*, generic substitution occurs very swiftly, and in the case of Intuniv Shire's market share was reduced from 100% to 9% within six months of generic entry. AG licenses represent a means by which the brand company can retain market share post generic entry, and these high rates of AG launches reflect the fact that brand companies realize incremental revenue from launching an AG into the market.

97. As noted above, upon information and belief, through Shire's agreements with TWi/Anchen and Actavis, Shire gave up substantial value by licensing TWi/Anchen's AG

launch at an artificially low royalty and/or by agreeing with Actavis not to launch an AG to compete with Actavis. Absent such anticompetitive terms, the Shire-Actavis settlement does not make economic sense.

98. Upon information and belief, Actavis earned approximately $110 million in profit from its generic Intuniv during its 180-day exclusivity period without AG competition. By contrast, a competing AG licensed by Shire would have roughly halved Actavis's profits on its generic Intuniv product. Thus, upon information and belief, Shire's commitment not to launch a competing AG was worth in excess of a large amount, $50 million, to Actavis.

99. Shire's reverse payment of tens of millions of dollars to Actavis vastly exceeded Shire's future anticipated litigation costs, which would have been minimal as the case was post-trial.

100. Further, as with Shire-TWi/Anchen settlement, the Shire-Actavis settlement included a consent judgment drafted by the parties that misleadingly sought to create the impression to other potential generic manufacturers and to other courts that Shire's Intuniv patents were valid and that Actavis's product actually infringed Shire's patents to conceal the true intent of the consent judgment.

101. Upon information and belief, the multi-year extension of Shire's Intuniv monopoly imposed a substantial cost on consumers and conferred an enormous benefit to Shire worth hundreds of millions of dollars, some of which was shared with TWi/Anchen and Actavis in exchange for allowing Shire to unlawfully extend its monopoly.

102. With the Shire-Actavis settlement consummated, other generic manufacturers saw little reason to spend resources litigating when they could in no event launch until 180 days after triggering Actavis's exclusivity and when Shire was willing to offer a license effective date that

coincided with 180 days after Actavis's entry. In this manner, Shire was able to buy off later challengers to avoid any ruling on the validity of Shire's Intuniv patents.

103. These reverse payment settlement agreements with TWi/Anchen and Actavis were fraudulently concealed from public, Plaintiff, and other Class Members, who would not have learned about these agreements or their anticompetitive effects through reasonable and ordinary diligence. The patent litigations proceeded almost entirely under seal (even court orders were sealed), and the various settlement agreements and other agreements are non-public documents that have never been made publicly available in their entirety. Indeed, the very intent of the settling parties in structuring the payments as non-cash transfers was to disguise as best as possible their true nature as payments in exchange for delay.

104. As with the Shire-TWi/Anchen settlement, the Shire-Actavis settlement was against Actavis's own self-interest inasmuch as what Actavis stood to obtain had Shire's patents been found to be invalid and/or not infringed. The only way it made sense was if Shire forewent launching its own AG product during Actavis's 180-day exclusivity period.

I. Effect on Interstate Commerce, Market Power and Competition

105. At all relevant times, Defendants manufactured, sold, and shipped Intuniv across state lines, including into Wisconsin.

106. At all relevant times, in connection with its sales of Intuniv, monies, contracts, bills, and business communications were transmitted continuously and uninterruptedly across state lines, including into Wisconsin.

107. At all relevant times, various devices were employed to commit the illegal acts described herein, including U.S. mail, interstate travel, interstate telephone communications, and interstate commerce. Defendants' complained-of activities occurred within the stream of, and have substantially affected, interstate commerce.

108. In this case, as alleged herein, there is direct proof of Defendants' market (or monopoly) power over the price of Intuniv. This direct proof includes, but is not limited to: (a) Shire's exclusion of competition from the market by way of its agreements with TWi/Anchen and Actavis; (b) the actual date of generic competition for Intuniv versus that expected; (c) price data demonstrating Shire's ability to raise its prices without losing sufficient sales to render the price increases unprofitable; and/or (d) the lack of non-Intuniv drug products that can be reasonably substituted for Intuniv.

109. The relevant product market is Intuniv and its generic equivalents in all dosage forms and strengths. In the alternative, the relevant product markets are (i) branded Intuniv, and (ii) generic Intuniv, each in all forms and strengths.

110. The relevant geographic market is nationwide. Through the illegal conduct described herein, Defendants were able to charge artificially high prices without losing substantial sales, and thus, by definition, maintained monopoly power over Intuniv products sold in the United States and Wisconsin.

111. Through the illegal conduct described herein, Defendants intentionally, purposefully, and successfully suppressed competition. Defendants' exclusionary conduct suppressed the sale of Intuniv in the United States and Wisconsin and unlawfully enabled Defendants to sell Intuniv Product at artificially inflated prices.

112. During the relevant time period, Plaintiff and Class Members purchased Intuniv Product indirectly from Defendants. As a result of Defendants' anticompetitive and illegal conduct, Plaintiff and Class Members were forced to pay more money in the form of higher patient co-pays for "brand name" medication even though it was precisely the same as the generic Intuniv products. This is because Plaintiff and Class Members were deprived of the

ability to purchase lower-priced generic Intuniv at competitive market prices. In addition, upon information and belief, Plaintiff or other Class Members paid more for generic Intuniv than they would have absent Defendants' anticompetitive conduct.

113. Thus, Plaintiff and the Class Members, as a result of Defendants' illegal conduct, have suffered monetary losses and damages.

J. Factual Allegations as to Named Plaintiff

114. Plaintiff Sherri Cummisford is a resident of Milwaukee County, Wisconsin . Plaintiff's minor child was prescribed Intuniv during the Class Period.

115. During the Class Period, Plaintiff Cummsiford had an insurance benefit that covered some but not all of the cost of prescription drugs. Upon information and belief, the co-pay amounts paid changed based on where a particular drug was placed on the insurer's formulary.

116. Upon information and belief, Plaintiff Cummisford was required to pay a higher co-pay for Intuniv than patients typically pay for drugs where a generic option is available, and – upon information and belief – the co-pay was more than Plaintiff would have paid had Defendants not engaged in the conduct alleged herein.

117. Plaintiff was an indirect purchaser of Intuniv.

K. Fraudulent Concealment and Tolling

118. Upon information and belief, Shire and Actavis each affirmatively concealed from Plaintiff and other Class Members their unlawful conduct. Shire and Actavis planned and implemented the unlawful schemes in private, and affirmatively strove to avoid discussing or disclosing the schemes, and took other actions to hide and conceal the unlawful conduct.

119. For instance, the patent infringement litigations proceeded mostly under seal, and the nature of these settlement agreements and related side deals and reverse payment

arrangements in order to delay generic entry were fraudulently concealed from the public, Plaintiff, and other Class Members.

120. Furthermore, Actavis's CEO misleadingly asserted – as quoted in Actavis's press release – that the Shire-Actavis settlement meant that the availability of generic Intuniv would be accelerated.

121. Shire's own press release regarding the TWi/Anchen settlement asserted that Shire would receive a "significant royalty" when in fact Shire's royalty was significantly depressed from what would have constituted a commercially reasonable arm's length royalty. TWi/Anchen never disclosed the terms or true nature of the arrangement, including the royalty.

122. Further, the actual settlement documents (or any other terms that were not publicly disclosed) have not been made available to full public scrutiny. Nor were the precise terms of these agreements ever revealed to Plaintiff or other Class Members. Shire and Actavis (and TWi/Anchen) never disclosed the anticompetitive negotiations and terms set forth above, as it was Shire's (and Actavis's) intention to deceive Plaintiff and other Class Members.

123. Because of the above, Plaintiff and other Class Members did not discover, nor would they discover through reasonable and ordinarily diligence, Shire's and Actavis's deceptive, fraudulent, anticompetitive, and unlawful conduct alleged herein. Shire's and Actavis's false and misleading explanations, or obfuscations, lulled Plaintiff and Class Members into believing that the prices paid for Intuniv were the result of competitive market forces rather than collusive or monopolistic, anticompetitive practices.

124. As a result of Shire's and Actavis's affirmative and other acts of concealment, any applicable statute of limitations affecting the rights of Plaintiff and other Class Members has been tolled. Plaintiff and/or other Class Members exercised reasonable diligence by among other

things promptly investigating and bringing the allegations contained herein. Despite these or other efforts, Plaintiff was unable to discover, and could not have discovered, the unlawful conduct alleged herein at the time it occurred or at an earlier time so as to enable this complaint to be filed sooner.

125. Defendants' unlawful conduct alleged herein and the effects thereof are continuing and, as a direct and proximate result, Plaintiff and Class Members have and continue to suffer ascertainable losses.

V. CLASS ALLEGATIONS

A. Class Definition

126. Plaintiff brings this action pursuant to Federal Rules of Civil Procedure 23(b)(2) and (b)(3) on behalf of herself and on behalf of the Class defined below. The proposed Class includes:

> **All persons who paid (for personal or household use) some or all of the purchase price for brand or generic Intuniv in the State of Wisconsin between October 5, 2012 and the present.**

127. Excluded from the Class are: (1) third-party payors; (2) persons and entities who purchased directly from Defendants; (3) persons and entities who purchased only for resale purposes; (4) "flat co-pay" "Cadillac Plan" customers who made purchases only via fixed dollar co-payments that do not vary between a branded pharmaceutical and a generic equivalent; (5) patients with insurance coverage including a flat-rate co-pay provision; (6) governmental entities; (7) Defendants, as well as their officers, directors, affiliates, legal representatives, employees, co-conspirators, successors, subsidiaries and assigns, and entities in which each Defendant has a controlling interest; and (8) the judge, justices, magistrates or judicial officers presiding over this matter.

128. Said definition may be further defined or amended by additional pleadings, evidentiary hearings, a class certification hearing, and orders of this Court.

B. Fed. R. Civ. P. 23(a) Factors

129. **Numerosity.** The members of the Class are so numerous that separate joinder of each member is impracticable. Plaintiff does not know the exact number of members in the Class, but based upon information and belief, Plaintiff reasonably believes that Class Members number at a minimum in the thousands.

130. **Commonality.** The claims of Plaintiff raise questions of law or fact common to the questions of law or fact raised by the claims of each member of the Class. Plaintiff's claims arise from the same practice or course of conduct that gives rise to the claims of the Class members. The questions of law and fact common to Plaintiff and the Class predominate over questions affecting only individual Class Members, and include, but are not limited to, the following:

- Whether Defendants' patent settlement agreements constitute illegal restraints of trade in violation of Section 1 of the Sherman Act and/or Wisconsin law.
- Whether Defendants' violations of Section 1 of the Sherman Act constitute violations of Wisconsin law;
- Whether Shire's patent infringement lawsuits filed against TWi/Anchen, Actavis and others were filed with the improper purpose of preventing entry of competing generic products into the market, in violation of Section 2 of the Sherman Act and/or Wisconsin law;
- Whether Defendants' violations of Section 2 of the Sherman Act constitute violations of Wisconsin law;
- Whether a relevant market needs to be defined in this case in light of the existence of direct evidence of any Defendant's power to exclude generic competition and set supracompetitive prices for Intuniv;
- If a relevant market needs to be defined, the definition of the relevant market for analyzing any Defendant's monopoly power, and whether any Defendant had monopoly power in the relevant market;

- Whether, independent of whether Defendants' conduct violated the Sherman Act, Defendants' conduct constitutes anticompetitive, unfair, fraudulent, and/or deceptive practices in violation of Wisconsin law; and/or

- Whether Plaintiff and the Class have been injured as a result of Defendants' anticompetitive, unfair, fraudulent, and/or deceptive conduct, and the amount of damages.

131. **Typicality.** The claims of Plaintiff are typical of the claims of each member of the Class. Defendants engaged in a standardized course of conduct affecting the Class Members, and Plaintiff's alleged injuries arise out of that conduct. All Class Members, including Plaintiff, have the same or similar injury to their property (i.e. paying higher prices for Intuniv) as a result of Defendants' anticompetitive conduct.

132. **Adequacy.** Plaintiff can fairly and adequately protect and represent the interests of each member of the Class. Plaintiff fits within the class definition and her interests do not conflict with the interest of the members of the Class she seeks to represent. Plaintiff is represented by experienced and able attorneys. The undersigned Class Counsel have litigated numerous class actions and complex cases and intend to prosecute this action vigorously for the benefit of the entire Class. Plaintiff and Class Counsel can and will fairly and adequately protect the interests of all members of the Class.

C. Fed. R. Civ. P. 23(b)(2) Factors

133. Defendants acted on grounds generally applicable to the entire Class, thereby making final injunctive relief and/or corresponding declaratory relief appropriate with respect to the Class as a whole. The prosecution of separate actions by individual Class Members would create the risk of inconsistent or varying adjudications with respect to individual members of the Class that would establish incompatible standards of conduct for Defendants.

134. Injunctive relief is necessary to prevent further anticompetitive conduct by Defendants. Money damages alone will not afford adequate and complete relief, and injunctive

relief is necessary to restrain Defendants from continuing to engage in conduct which restrains, suppresses, and/or eliminates competition in the United States and Wisconsin for the sale of Intuniv.

D. Fed. R. Civ. P. 23(b)(3) Factors

135. **Common issues predominate:** As set forth in detail above, common issues of fact and law predominate because all of Plaintiff's claims are based on identical anticompetitive conduct.

136. **Superiority:** Additionally, a class action is superior to other available methods for fair and efficient adjudication of the controversy. The damages sought by each Class Member are such that individual prosecution would prove burdensome and expensive given the complex and extensive litigation necessitated by Defendants' conduct. It would be virtually impossible for the members of the Class to effectively redress the wrongs done to them on an individual basis. Even if the members of the Class themselves could afford such individual litigation, it would be an unnecessary burden on the courts.

137. The trial and litigation of Plaintiff's claims are manageable. Individualized litigation presents a potential for inconsistent or contradictory judgments and increases the delay and expense to all parties and to the court system. By contrast, the class action device will result in substantial benefits to the litigants and the Court by allowing the Court to resolve numerous individual claims and the legal and factual issues presented by Defendants' conduct based upon a single set of proof in just one case.

138. Further, Defendants have acted on grounds generally applicable to the Class, thereby making final injunctive relief with respect to the Class as a whole appropriate. Moreover, on information and belief, Plaintiff alleges that the conduct complained of herein is substantially likely to continue in the future if an injunction is not entered.

139. **Notice to the Class:** Notice to the Class sufficient to meet or exceed these standard of due process can may be made by publication.

VI. CAUSES OF ACTION

A. First Cause of Action: Unreasonable Restraint of Trade Under State Law (premised on Section 1 of the Sherman Act) (against all Defendants)

140. Plaintiff repeats and realleges the allegations set forth above, and incorporates the same as if set forth herein at length.

141. Defendants entered into reverse payment settlement agreements to suppress generic competition with Intuniv and/or its generic equivalent. The reverse payment settlement agreements alleged herein, individually and collectively, constitute a contract, combination, and/or conspiracy that substantially, unreasonably, and unduly restrained trade.

142. Defendants violated Section 1 of the Sherman Act by engaging in the unlawful, anticompetitive conduct set forth herein. Defendants have unreasonably restrained trade and interstate commerce in the relevant product market in violation of Section 1 of the Sherman Act.

143. Shire's agreements with TWi/Anchen and Actavis, individually and collectively, were comprised of large and unjustifiable payments from Shire to Actavis (and from Shire to TWi/Anchen), each of whom in turn agreed to delay entry into the market, and/or not to compete vigorously. As such, each agreement, individually and collectively, is an unreasonable restraint of trade. The agreements and various side deals were for no purpose other than to delay the generic manufacturers' entry into the drug market and offered no procompetitive benefits.

144. Competition, including price competition at the consumer level for Intuniv (through the emergence of generic alternatives) will continue to be restrained, suppressed or eliminated as a result of Defendants' anticompetitive conduct described herein. The actual

adverse effects of Shire's illicit agreements with TWi/Anchen and Actavis include, but are not limited to:

- Shire's control of the Intuniv market;
- The delayed entry of generic competition into the Intuniv market;
- Higher prices for brand Intuniv (due to market unavailability of generic Intuniv); and
- Higher prices for generic Intuniv (due to delayed market availability of generic Intuniv).

145. The agreements, individually and collectively, were *per se* anticompetitive for these reasons. Alternatively, the agreements, individually and collectively, constitute an unreasonable restraint under "quick look" or "rule of reason" analysis, the relevant market being Intuniv and generic equivalents sold nationwide, or the alternative markets for brand Intuniv and for generic Intuniv.

146. Competitors, actual and potential, have been, and will continue to be, restrained from vigorously competing with one another for selling Intuniv as a result of Defendants' anti-competitive conduct.

147. Indirect purchasers (including Plaintiff and members of the putative Class), have been injured in their business and property because they have been deprived of choice, and have paid inflated prices for Intuniv (or paid higher co-pays for brand name medications), which they otherwise would not have had to pay in the absence of Defendants' anticompetitive conduct. Plaintiff's and the Class's injuries flow from Defendants' unlawful conduct.

148. There is and was no legitimate, non-pretextual, procompetitive justification for the agreements, individually or collectively, that outweighs the harmful effects alleged herein. Even if there was such justification, the agreements, individually and collectively, are broader than necessary to achieve any procompetitive purpose.

149. Defendants' violation of Section 1 of the Sherman Act constitutes a violation of the Wisconsin Antitrust Act, § 133.03 *et seq.*

150. Plaintiff Cummisford is a "person" within the meaning of Wis. Stat. § 133.02.

151. Each Defendant is a "person" within the meaning of Wis. Stat. § 133.02.

152. Defendants' conduct constitutes an "unlawful contract" under Wis. Stat. § 133.03.

153. Because of Defendants' violations of Section 1 of the Sherman Act (and hence the state laws alleged herein), consumers (including Plaintiff and the Class) were deprived of a less expensive generic product, and were forced to purchase a more expensive brand name (or generic) product. These are the types of injuries the Sherman Act, and state laws alleged herein, seek to prevent.

154. As a direct and proximate result of Defendants' violations of Section 1 of the Sherman Act (and hence the state laws alleged herein), Plaintiff and the Class have suffered a loss of money and suffered actual damages.

155. There is no federal or state law which affirmatively authorizes Defendants to engage in the unfair conduct alleged throughout this Complaint.

156. In addition to actual damages, Plaintiff and the Class are entitled to declaratory and injunctive relief as well as reasonable attorney's fees and costs.

B. Second Cause of Action: Unlawful Monopoly Under State Law (premised on Section 2 of the Sherman Act) (against Shire)

157. Plaintiff repeats and realleges the allegations set forth above, and incorporate the same as if set forth herein at length.

158. Shire violated Section 2 of the Sherman Act. Shire successfully gained and exercised unlawful monopoly power over the price of Intuniv, and over the relevant market—Intuniv and its generic equivalents—nationwide and in the State of Wisconsin. But for

Shire's exclusionary practices, as set forth above, Shire would not have been able to maintain its monopoly power over the price of Intuniv in the relevant market.

159. By violating Section 2 of the Sherman Act, Shire has engaged in an unfair, unlawful, unconscionable, and/or deceptive practice in violation of Wisconsin law, and caused Plaintiff and the Class to suffer ascertainable losses.

160. Shire's violation of Section 2 of the Sherman Act is further illustrated by its successful attempt to exert an illegal monopoly over the price of Intuniv and over the relevant market. Shire entered into illegal reverse payment settlement agreements to delay generic entry.

161. During the relevant period, Shire willfully and unlawfully maintained its monopoly power by excluding and delaying competition from the market for Intuniv. The goal, purpose and/or effect of the scheme was to prevent and delay market entry of generic Intuniv competitors, who would have sold generic versions nationwide and in Wisconsin at prices significantly below Shire's prices for Intuniv, and therefore would have taken most of Shire's market share. Such generic competition would have effectively caused the average market price of Intuniv to decline dramatically.

162. Shire has willfully acquired and/or maintained its monopoly power over the market for the sale of Intuniv, not through superior skill , quality of product, business acumen, or enterprise, but rather through the foregoing anticompetitive and exclusionary conduct. Shire's conduct ran afoul of Section 2 of the Sherman Act.

163. There is no appropriate, procompetitive, or legitimate business justification for the actions and conduct that have facilitated Shire's monopolization of the United States market for the sale of Intuniv.

164. Plaintiff and members of the putative Class have been injured because they have been deprived of choice, and have paid inflated prices for Intuniv or generic Intuniv, which they otherwise would not have had to pay in the absence of Shire's anticompetitive conduct. Plaintiff's and the Class's injuries flow from Shire's unlawful conduct.

165. Shire's violation of Section 2 of the Sherman Act constitute a violation of the Wisconsin Antitrust Act, § 133.03 *et seq.*

166. Plaintiff Cummisford is a "person" within the meaning of Wis. Stat. § 133.02.

167. Each Defendant is a "person" within the meaning of Wis. Stat. § 133.02.

168. Defendants' conduct constitutes an "unlawful contract" under Wis. Stat. § 133.03.

169. Because of Shire's violation of Section 2 of the Sherman Act (and hence the state laws alleged herein), consumers (including Plaintiff and the Class) were deprived of a less expensive generic product, and were forced to purchase a more expensive brand name product (and later a more expensive generic product). These are the types of injuries the Sherman Act seeks to prevent.

170. As a direct and proximate result of Shire's violations of Section 2 of the Sherman Act (and hence the state laws alleged herein), Plaintiff and the Class have suffered a loss of money and suffered actual damages.

171. In addition to actual damages, Plaintiff and the Class are entitled to declaratory and injunctive relief as well as reasonable attorney's fees and costs.

C. Third Cause of Action: Unlawful Attempted Monopolization Under State Law (premised on Section 2 of the Sherman Act) (against Shire)

172. Plaintiff repeats and realleges the allegations set forth above, and incorporates the same as if set forth herein at length.

173. Shire violated Section 2 of the Sherman Act. Shire unlawfully attempted to gain and exercise monopoly power over the price of Intuniv, and over the relevant market—Intuniv and its generic equivalents—nationwide and in the state of Wisconsin. Shire has or had a dangerous probability of so obtaining unlawful monopoly power, and specific intent to do so. But for Shire's exclusionary practices, as set forth above, Shire would not have been able to achieve or to maintain its monopoly power over the price of Intuniv in the relevant market.

174. By violating Section 2 of the Sherman Act, Shire has engaged in an unfair, unlawful, unconscionable, and/or deceptive practice in violation of Wisconsin law, and caused Plaintiff and the Class to suffer ascertainable losses.

175. Shire's violation of Section 2 of the Sherman Act is further illustrated by its attempt to exert an illegal monopoly over the price of Intuniv and over the relevant market. Shire entered into illegal reverse payment settlement agreements to delay generic entry.

176. During the relevant period, Shire willfully and unlawfully attempted to gain unlawful monopoly power by excluding and delaying competition from the market for Intuniv. The goal, purpose and/or effect of the scheme was to prevent and delay market entry of generic Intuniv competitors, who would have sold generic versions nationwide and at prices significantly below Shire's prices for Intuniv, and therefore would have taken most of Shire's market share. Such generic competition would have effectively caused the average market price of Intuniv to decline dramatically.

177. Shire has willfully attempted to acquire and/or to maintain its monopoly power over the market for the sale of Intuniv, not through superior skill, quality of product, business acumen, or enterprise, but rather through the foregoing anticompetitive and exclusionary conduct. Shire's conduct ran afoul of Section 2 of the Sherman Act.

178. There is no appropriate, procompetitive, or legitimate business justification for the actions and conduct that have facilitated Shire's attempted monopolization of the United States market for the sale of Intuniv.

179. Plaintiffs and members of the putative Class have been injured because they have been deprived of choice, and have paid inflated prices for Intuniv or generic Intuniv, which they otherwise would not have had to pay in the absence of Shire's anticompetitive conduct. Plaintiff's and the Class's injuries flow from Shire's unlawful conduct.

180. Shire's violation of Section 2 of the Sherman Act constitute a violation of the Wisconsin Antitrust Act, § 133.03 *et seq.*

181. Plaintiff Cummsiford is a "person" within the meaning of Wis. Stat. § 133.02.

182. Each Defendant is a "person" within the meaning of Wis. Stat. § 133.02.

183. Defendants' conduct constitutes an "unlawful contract" under Wis. Stat. § 133.03.

184. As a direct and proximate result of Shire's violations of Section 2 of the Sherman Act (and hence the state laws alleged herein), Plaintiff and the Class have suffered a loss of money and suffered actual damages.

185. In addition to actual damages, Plaintiff and the Class are entitled to declaratory and injunctive relief as well as reasonable attorney's fees and costs.

D. Fourth Cause of Action: Unlawful Conspiracy to Monopolize Under State Law (premised on Section 2 of the Sherman Act) (against all Defendants)

186. Plaintiff repeats and realleges the allegations set forth above, and incorporate the same as if set forth herein at length.

187. Defendants violated Section 2 of the Sherman Act. Defendants conspired to gain and exercise unlawful monopoly power, either collectively or individually, over the price of

Intuniv, and over the relevant market—Intuniv and its generic equivalents—nationwide and in the State of Wisconsin.

188. By violating Section 2 of the Sherman Act, Defendants have engaged in an unfair, unlawful, unconscionable, and/or deceptive practice in violation of Wisconsin law, and caused Plaintiff and the Class to suffer ascertainable losses.

189. Defendants' violation of Section 2 of the Sherman Act is further illustrated by Shire's and/or Defendants' exertion of illegal monopoly over the price of Intuniv and its generic equivalents, and over the relevant market(s), including in the alternative the market for brand Intuniv and the market for generic Intuniv. Defendants entered into illegal reverse payment settlement agreements to delay generic entry.

190. During the relevant period, Defendants willfully and unlawfully conspired to obtain or maintain Shire's and/or Defendants' monopoly power by excluding and delaying competition from the market for Intuniv and its generic equivalents. Each Defendant manifested an intention to participate in a common scheme as alleged herein. The goal, purpose and/or effect of the scheme was to prevent and delay market entry of generic Intuniv competitors, who would have sold generic versions nationwide and in Wisconsin at prices significantly below Shire and/or Defendants' prices for Intuniv and its generic equivalents, and therefore would have taken most of Shire and/or Defendants' market share. Such generic competition would have effectively caused the average market price of Intuniv and its generic equivalents to decline dramatically.

191. There is no appropriate, procompetitive, or legitimate business justification for the actions and conduct that have facilitated Defendants' conspiracy to monopolize the United States market for the sale of Intuniv and its generic equivalents.

192. Plaintiff and members of the putative Class have been injured because they have been deprived of choice and have paid inflated prices for Intuniv or generic Intuniv, which they otherwise would not have had to pay in the absence of Defendants' anticompetitive conduct. Plaintiff's and the Class's injuries flow from Defendants' unlawful conduct.

193. Defendants' violation of Section 2 of the Sherman Act constitutes a violation of the Wisconsin Antitrust Act, § 133.03 *et seq.*

194. Plaintiff Cummsiford is a "person" within the meaning of Wis. Stat. § 133.02.

195. Each Defendant is a "person" within the meaning of Wis. Stat. § 133.02.

196. Defendants' conduct constitutes an "unlawful contract" under Wis. Stat. § 133.03.

197. Because of Defendants' violation of Section 2 of the Sherman Act (and hence the state laws alleged herein), consumers (including Plaintiff and the Class) were deprived of a less expensive generic product, and were forced to purchase a more expensive brand name product (and later a more expensive generic product). These are the types of injuries the Sherman Act seeks to prevent.

198. As a direct and proximate result of Defendants' violations of Section 2 of the Sherman Act (and hence the state laws alleged herein), Plaintiff and the Class have suffered a loss of money and suffered actual damages.

199. In addition to actual damages, Plaintiff and the Class are entitled to declaratory and injunctive relief as well as reasonable attorney's fees and costs.

E. Fifth Cause of Action: Violation of State Consumer Protection and Antitrust Law (not premised on violations of Sherman Act) (against all Defendants)

200. Plaintiff repeats and realleges the allegations set forth above, and incorporate the same as if set forth herein at length.

201. Independent of whether Defendants' conduct violated the Sherman Act, Defendants' conduct, as described throughout the Complaint, constitutes unlawful, unfair, fraudulent, unconscionable, anticompetitive, and/or deceptive practices in violation of the Wisconsin Antitrust Act, § 133.03 *et seq.*

202. Plaintiff Cummsiford is a "person" within the meaning of Wis. Stat. § 133.02.

203. Each Defendant is a "person" within the meaning of Wis. Stat. § 133.02.

204. Defendants' conduct constitutes an "unlawful contract" under Wis. Stat. § 133.03.

205. By utilizing, inter alia, sham patent litigation and anticompetitive settlements to delay the entry into the market of generic version of Intuniv, Defendants engaged in deceptive, fraudulent, unconscionable, anticompetitive, and/or unfair trade practices that caused Plaintiff and the Class to pay more for branded and subsequently generic Intuniv than they would have but for this wrongful conduct.

206. Defendants' deceptive, fraudulent, unconscionable, anticompetitive, and/or unfair practices, as described herein, offend established public policy, are unconscionable, and caused ascertainable losses to consumers. Defendants forced users of their prescription medication, who had no reasonable alternatives, to pay higher prices for branded and generic Intuniv well into the period in which generic alternatives to Intuniv were available. Defendants were motivated solely by profit at the expense of Plaintiff and the Class.

207. As a direct and proximate result of Defendants' unlawful practices (including practices prohibited by the enunciated state antitrust laws, as well as the enunciated state consumer protection laws), Plaintiff and the Class have suffered a loss of money and suffered actual damages.

208. In addition to actual damages, Plaintiff and the Class are entitled to treble damages, declaratory and injunctive relief, as well as reasonable attorney's fees and costs.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of herself and on behalf of the members of the Class defined herein, request judgment and relief on all Causes of Action as follows:

(a). An order certifying that the action may be maintained as a Class Action;

(b). The acts alleged herein be adjudged and decreed to be an unfair, deceptive, anticompetitive, unconscionable and/or fraudulent business practices violating Wisconsin law;

(c). That judgment be entered against Defendants, and each of them jointly and severally, for damages as a result of Defendants' violations of Wisconsin law;

(d). That judgment be entered against Defendants and in favor of Plaintiff and the Class on the Plaintiffs' Wisconsin law claims, for treble damages, actual and consequential damages, and equitable relief, including restitution and restitutionary disgorgement;

(e). Actual, double, or treble damages, as appropriate;

(f). For pre and post-judgment interest from the date of filing this suit;

(g). Reasonable attorneys' fees;

(h). Costs of this suit; and

(i). Such other and further relief as the Court may deem necessary or appropriate.

JURY TRIAL DEMANDED

Dated: November 23, 2016

Respectfully submitted,

/s/ John D. Blythin

Shpetim Ademi (SBN 1026973)
John D. Blythin (SBN 1046105)
Mark A. Eldridge (SBN 1089944)
Denise L. Morris (SBN 1097911)
ADEMI & O'REILLY, LLP
3620 East Layton Avenue
Cudahy, WI 53110
(414) 482-8000
(414) 482-8001 (fax)
sademi@ademilaw.com
jblythin@ademilaw.com
meldridge@ademilaw.com
dmorris@ademilaw.com

Allan Kanner, Esquire (LA Bar No. 20580) (*PHV pending*)
Conlee S. Whiteley, Esquire (LA Bar No. 20580) (*PHV pending)*
Marshall Perkins, Esquire (LA Bar No. 36979) (*PHV pending)*
Layne Hilton, Esquire (LA Bar No. 36990) (*PHV pending)*
KANNER & WHITELEY, LLC
701 Camp Street
New Orleans, LA 70130
Phone: (504) 524-5777
Email: a.kanner@kanner-law.com
c.whiteley@kanner-law.com
m.perkins@kanner-law.com
l.hilton@kanner-law.com

Ruben Honik, Esquire (PA Bar No. 33109) *(PHV pending)*
David J. Stanoch, Esquire (PA Bar. Bo. 91342) *(PHV pending)*
GOLOMB & HONIK, P.C.
1515 Market Street, Suite 1100
Philadelphia, PA 19102
Phone: (215) 985-9177
Fax: (215) 985-4169
Email: rhonik@golombhonik.com
dstanoch@golombhonik.com

Attorneys for Plaintiff and the Proposed Class